

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejects claims 1-3, 7-11, and 15 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,010,183 to Macfarlane ("Macfarlane I"). Office Action at page 2, item No. 3. Addressing applicant's arguments, the Examiner contends that Macfarlane I "specifically describes that proteinase K can be used during the addition of the cationic detergent (col. 5, line 16) and the use of a buffer is described in the examples." See the paragraph bridging pages 2 and 3.

Applicant respectfully traverses the rejection. For a reference to anticipate the claimed invention under 35 U.S.C. § 102, the reference must describe the invention such that "each and every limitation is found either expressly or inherently" within it. *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370, 62 USPQ2d 1865, 1869 (Fed. Cir. 2002) (citation omitted); see also Manual of Patent Examining Procedure § 2131 (8th ed. 2001) ("MPEP") ("to anticipate a claim, the reference must teach every element of the claim").

At the outset, Applicant respectfully submits that releasing of nucleic acids is distinct from precipitation or isolation of released nucleic acids. See the present specification, e.g., page 2, lines 11-12 ("The released nucleic acids are then selectively precipitated from solution"); page 16, lines 6-11 (where a composition is used to release nucleic acids from the biological sample); page 17, lines 3-4 (where the released nucleic acid is then isolated). Claim 1 recites a composition for releasing nucleic acids from a biological sample that comprises at least one cationic surfactant, at least one protease, and a buffer. Claims 2-3, 7-11, and 15 all ultimately depend from claim 1.

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Macfarlane I does discuss the use of a cationic detergent in a releasing step. It also discusses the possibility of using a hydrolytic enzyme to disperse tissues before releasing nucleic acids. However, it fails to disclose the use of a buffer in the composition used for releasing nucleic acids. The Examiner alleges that the use of buffer is described in the examples of Macfarlane I. As applicant pointed out in the last response, the buffer in the example of Macfarlane I is used for resuspending nucleic acids after they have been released and precipitated. The examples in Macfarlane I fail to discuss use of a buffer in a composition for releasing nucleic acids.

Specifically, in Example 1 of Macfarlane I, for releasing nucleic acids, cells were treated with an aqueous solution containing 1% of cationic surfactant 16-BAC, followed by ethanol/ammonium acetate. There is no discussion of this solution having buffering capacity. Only after the releasing step was the surfactant complex pellet dissolved in a Tris-HCl buffer at pH 7.5. Similarly, Examples 2 and 3 fail to discuss releasing compositions that contain buffers.

Accordingly the Examiner fails to establish that Macfarlane I shows a composition for releasing nucleic acids from a biological sample comprising at least one cationic surfactant, at least one protease, and a buffer. Therefore, the Examiner has failed to establish that Macfarlane I anticipates claim 1. Claims 2, 3, 7-11 and 15 ultimately depend from claim 1, and for at least the reasons presented above, are not anticipated by Macfarlane I. Moreover, Applicant need not address the rest of the Examiner's contention concerning Macfarlane I regarding proteinase K. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Reconsideration and withdrawal of the § 102 rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a).

The Examiner rejects claims 1-25 and 88-113 under 35 U.S.C. § 103(a) as allegedly being obvious over Macfarlane I in view of U.S. Patent No. 5,728,822 to Macfarlane ("Macfarlane II"). Office Action, page 2-3, item No. 5.

Applicant respectfully traverses. As discussed above, the Examiner fails to show that Macfarlane I discloses a composition for releasing nucleic acids from a biological sample, comprising at least one cationic surfactant, at least one protease, and a buffer. Moreover, the Examiner fails to establish that Macfarlane I would have suggested such a composition. Macfarlane II does not remedy the deficiencies of Macfarlane I.

Further, Macfarlane II does not teach and would not have suggested a composition for releasing nucleic acids from a biological sample, comprising at least one cationic surfactant, at least one protease, and a buffer.

Thus, the Examiner has failed to establish that the combination of Macfarlane I and Macfarlane II would have rendered obvious any of the rejected claims. Moreover, applicant need not address the Examiner's contentions concerning the combination of Macfarlene I and Macfarlane II with respect to other limitations of certain dependent claims. By not addressing those contentions, Applicant in no way acquiesces to those contentions.

Applicant respectfully requests the reconsideration and withdrawal of the § 103 rejection.

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Conclusion

Applicant respectfully asserts that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance, Applicant requests that the Examiner call the undersigned (650 849-6620) to arrange an interview prior to taking action.

Please charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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